REMARKS

Claims 1-3, 5, 9, 12-14 and 16 were rejected under 35 U.S.C. §103(a) as being unpatentable over US Pat. 5,191,885 (Bilof et al.) in view of US Pat. 5,830,144 (Vesely). Amended Claim 1 describes a system providing cardiac stimulation in combination with an endoscopic imaging probe, comprising a disposable, removable sheath of a flexible membrane material sized to slidably cover the distal transesophageal portion of an endoscopic imaging probe and permit transesophageal ultrasonic imaging by the endoscopic imaging probe within the sheath; a cardiac stimulation electrical conductor integrated in the sheath; and an electrical cable, attached to the cardiac stimulation electrical conductor and extending from the sheath, and adapted to be connected to an external defibrillator. A system of the present invention provides a removable sheath with a cardiac stimulation electrical conductor that slides over and covers the distal transesophageal portion of a transesophageal echocardiography (TEE) ultrasound probe. The electrode enables cardiac stimulation such as defibrillation to be performed from at least one electrode within the esophagus, just behind the heart. The sheath allows ultrasonic imaging of the heart by the probe covered by the sheath so that blood clots can be identified if present in the atria of the heart before and after cardiac stimulation. Significantly, the sheath covers the distal transesophageal portion of the probe and can provide a sterile cover for the probe during the procedure. As is well known, TEE ultrasound probes can be degraded by repeated sterilization and it is preferable to use less harsh disinfectants for ultrasound probes. The sheath of the present invention can be sterilized to provide a sterile cover for a disinfected probe, enabling the life of the expensive TEE ultrasound probe to be prolonged. Since the sheath with

its electrical conductor and cable is very simple and of low cost, it can be disposed of following the procedure.

Bilof et al. propose an electrode structure 10 which can be adhesively attached to the outside of an imaging probe to provide defibrillation pulses. Bilof et al. state in column 4, lines 16-18 that the electrode structure must be attached about 10 centimeters away from the ultrasound transmitter and receiver 52 of the probe so as not to interfere with ultrasonic transmission and reception. As the Examiner notes, the Bilof et al. electrode structure is not a sheath and provides no enclosing cover. Vesely is cited to provide this missing element. While Vesely shows a sheath with a closed end in one embodiment, the preferred embodiment is open at the distal end so that diagnostic or therapeutic components such as ultrasound transducers can remain active and unobstructed, as stated at col. 3, lines 47-50 and col. 4, lines 38-40. Like Bilof et al., Vesely keeps his sheath clear of the diagnostic transducer components at the distal end of the instrument 10 with which it is used. By contrast, the present claimed invention permits transesophageal ultrasonic imaging by the TEE probe which is covered distally by the sheath. As can be readily seen, providing a sterile cover for the probe is not contemplated by either Bilof et al. or Vesely.

The Vesely sheath is seen to carry many small ultrasonic transducers 30 which are used to send and receive ultrasonic tracking signals. These low level ultrasonic tracking signals are far removed from the high energy pulses used for cardiac stimulation, such as the 100 to 400 Joule pulses mentioned on page 7 of the present application. The Vesely patent would not suggest to one skilled in the art that a thin membrane sheath could be used to carry cardiac stimulation electrodes. Furthermore, the low energy Vesely transducers 30 are said to be imbedded inside the sheath walls 28A and 28B (col. 3, lines 52-53), not on the surface skin of the sheath as high energy

cardiac stimulation electrodes would be. See page 7, paragraph 21 of the present application.

The Examiner refers to col. 4, lines 9-12 of Vesely for the proposition that transesophageal ultrasonic imaging can be performed by the endoscopic imaging probe within the sheath. However, the cited passage does not say this. The passage states only that the signals from the transducers 30 of the sheath 20 are communicated to a 3-D tracking and imaging system. There is no indication that the signals from the transducers 30 are useful for anything other than tracking; imaging with these transducers is not contemplated. There is no suggestion at all of imaging by the instrument 10 from within the sheath.

Furthermore, Vesely stresses that the sheath should be kept away from the treatment area of the body such as the instruction to slide the sheath upward along the shaft and out of the way of the treatment area in col. 5, lines 13-15. The sheath is to be used only to track the instrument 10 as it approaches the treatment area. Once there, the sheath is to be manipulated to slide it out of the way. Clearly, this cannot be done if the end of the sheath were closed.

For all of these reasons it is respectfully submitted that the combination of Bilof et al. and Vesely cannot render amended Claim 1 obvious. Since Claims 2, 3, 5, 9, 12-14 and 16 all depend from Claim 1, it is respectfully submitted that these claims are patentable by reason of this dependency.

Claim 6 was rejected under §103(a) as unpatentable over Bilof et al. and Vesely in view of US Pat. 4,640,298 (Pless et al.) Pless et al. was cited for its showing of an inflatable balloon behind a conductor. Pless et al. shows an electrode probe for transesophageal pacing. The Pless et al. probe performs no imaging and has no sheath. Consequently it adds nothing to Bilof et al. and Vesely that would limit the patentability of Claim 1 as discussed above. Since Claim 6

depends from Claim 1, it is respectfully submitted that Claim 6 is patentable by reason of this dependency.

Claim 10 was rejected under §103(a) as unpatentable over Bilof et al. and Vesely in view of US Pat. 5,588,432 (Crowley). Crowley was cited for the proposition that conductors can be acoustically transparent. Crowley's device is an intravascular ultrasonic catheter, with one embodiment having electrodes 300 for electrophysiology or ablation. The outer tube of the ultrasonic catheter is sonolucent, as the ultrasound transducer 308 transmits and receives through the tube. This is easy to accomplish by virtue of the small size of an intravascular catheter; Crowley prefers that his catheter be six french in size or less. The electrodes 300 are fabricated on the outside of the catheter tube in a complex vacuum deposition process described in col. 14, line 41 through col. 16, line 10. The end product is essentially one described by Bilof et al., who say that their electrode structure 60 can be permanently affixed to their probe 10. Crowley thus is to the same effect as Bilof et al. when applied to Claim 1. Crowley does not suggest a sheath with a cardiac stimulation conductor which can slide over a probe prior to use and be removed at the end of the procedure, leaving the imaging probe intact after removal. This is because the sonolucent tube of Crowley is in fact the outer body of Crowley's probe. Since Crowley in combination with the other citations cannot render Claim 1 unpatentable it is respectfully submitted that Claim 10 is patentable over the combined citations by reason of its dependency on Claim 1.

In view of the foregoing amendment and remarks it is respectfully submitted that amended Claim 1 is patentable over Bilof et al., Vesely, Pless et al., and Crowley. It is therefore respectfully requested that the rejection of Claim 1 and its dependent Claims 2, 3, 5, 6, 9, 10, 12-14 and 16 under 35 U.S.C. §103(a) be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

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